

Fig 1

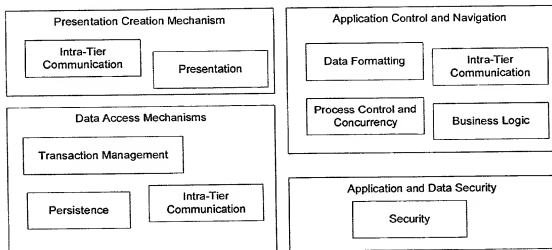


Fig 2

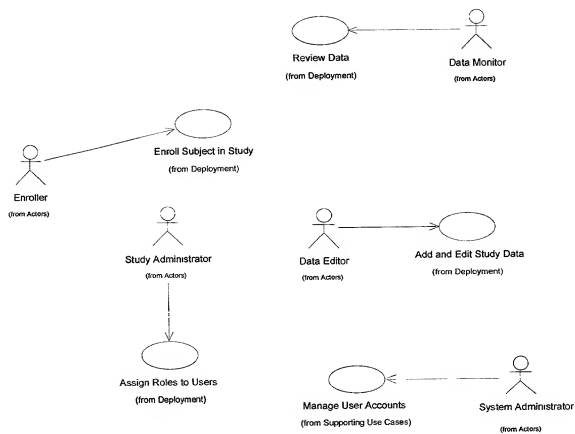


Fig 3

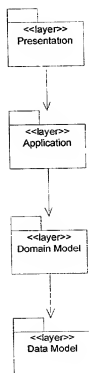


Fig 4

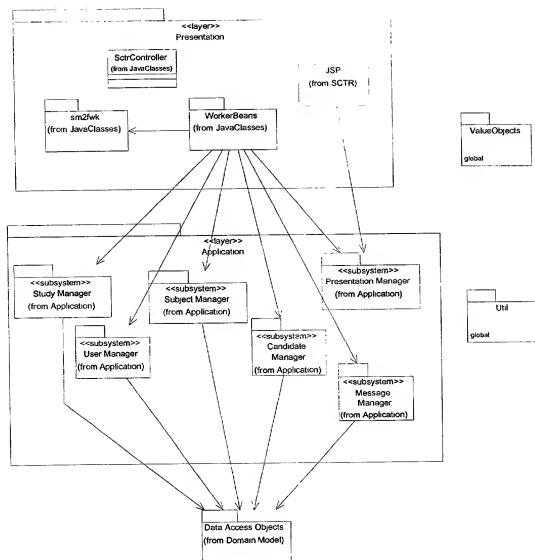


Fig 5

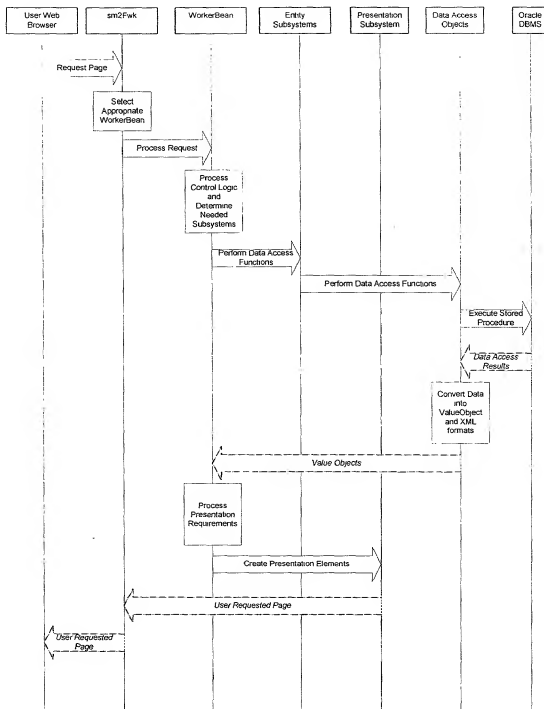


Fig 6

Login Function

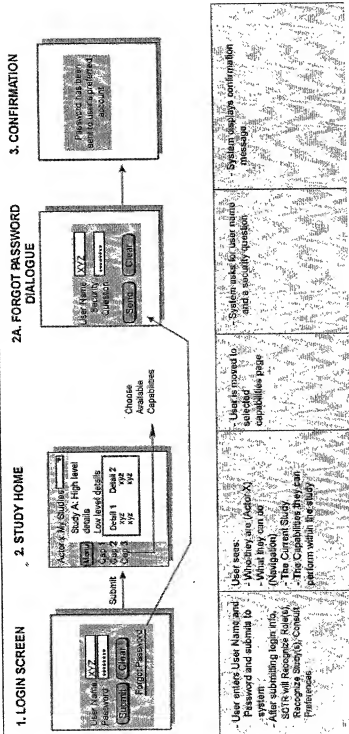


Fig 7

20E2T0"5Z95500T

SPONSORED BY THE
ALBERTO VILAR CENTER

SCTR Mail | Preferences | Help | Logout

User: Robert Hotchkiss, MD

Search:

Last Name

GO

Study Home Administration Register

Study: 443599 Basal Joint Arthritis

Study Home

Summary

PI: Robert Hotchkiss, MD
Collaborators: 6
Enrolled Subjects: 133
Disenrolled Subjects: 10
Status: Active
Start Date: 09/24/2001
Last Modified: 09/25/2001

Study Alerts

08/12/2001 Subject 123442 Disenrolled from Study
07/23/2001 Collaborator Walter Reed Data Set Editability Suspended
06/18/2001 Enrollment for Basal Joint Arthritis Study
05/13/2001 Enrollment Opened For Fracture Callus Study
05/05/2001 Subject 234558 Enrolled Into Basal Joint Arthritis Study

View All SCTR Mail

Reference Study Material

The files below represent background material for the study or points of information that may prove useful to the collaboration effort.

Author	Title	Time	Collected	Modified	Action
Robert Hotchkiss, MD	NIH Grant Application		File Uploaded	10/01/2001	
Tim Wright, MD	IRB Submission		File Uploaded	10/01/2001	
Robert Hotchkiss, MD	IRB Consent Form		File Uploaded	10/01/2001	
Robert Hotchkiss, MD	Surgical Technique Movie		Generic URL	10/01/2001	

Appendix Reference Study Material

Change Studies
View All Studies

SCTR
SPONSORED BY THE
ALBERTO VILAR CENTER

User: Robert Hotchkiss, MD

Search:

Last Name

GO

Study Home Administration Register

Study: 443599 Basal Joint Arthritis

Summary

PI: Robert Hotchkiss, MD
Collaborators: 6
Enrolled Subjects: 133
Disenrolled Subjects: 10
Status: Active
Start Date: 09/24/2001
Last Modified: 09/25/2001

Study Alerts

08/12/2001 Subject 123442 Disenrolled from Study
07/23/2001 Collaborator Walter Reed Data Set Editability Suspended
06/18/2001 Enrollment for Basal Joint Arthritis Study
05/13/2001 Enrollment Opened For Fracture Callus Study
05/05/2001 Subject 234558 Enrolled Into Basal Joint Arthritis Study

View All SCTR Mail

Reference Study Material

The files below represent background material for the study or points of information that may prove useful to the collaboration effort.

Author	Title	Time	Collected	Modified	Action
Robert Hotchkiss, MD	NIH Grant Application		File Uploaded	10/01/2001	
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Robert Hotchkiss, MD	IRB Consent Form		File Uploaded	10/01/2001	
Robert Hotchkiss, MD	Surgical Technique Movie		Generic URL	10/01/2001	

Appendix Reference Study Material

Change Studies
View All Studies

SCTR
SPONSORED BY THE
ALBERTO VILAR CENTER

User: Robert Hotchkiss, MD

Search:

Last Name

GO

Study Home Administration Register

Study: 443599 Basal Joint Arthritis

Summary

PI: Robert Hotchkiss, MD
Collaborators: 6
Enrolled Subjects: 133
Disenrolled Subjects: 10
Status: Active
Start Date: 09/24/2001
Last Modified: 09/25/2001

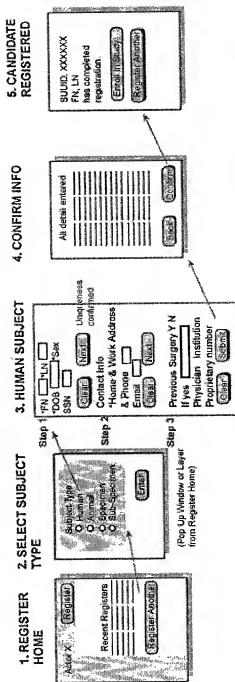
Study Alerts

08/12/2001 Subject 123442 Disenrolled from Study
07/23/2001 Collaborator Walter Reed Data Set Editability Suspended
06/18/2001 Enrollment for Basal Joint Arthritis Study
05/13/2001 Enrollment Opened For Fracture Callus Study
05/05/2001 Subject 234558 Enrolled Into Basal Joint Arthritis Study

View All SCTR Mail

Fig 8

Register candidate Subject Function



<ul style="list-style-type: none"> - Register function is selected - Always available to those with the capability 	<ul style="list-style-type: none"> - Pick subject type and click enter 	<ul style="list-style-type: none"> - This is a Wizard like process - Step 1 is basic info that leads to uniqueness confirmation - All required fields will be marked - Specimen or Sub-Specimen are Register Candidates Specimen 	<ul style="list-style-type: none"> - If entry is unique, all detail is presented for confirmation - The user chooses back to change or confirm to register 	<ul style="list-style-type: none"> - An SUJID is generated and the subject is in the pool - Edit the record - Move on to the next one - Enter it a study (potentially pre-enroll)
--	---	--	--	---

Fig 9

Register Specimen Function

6. SPECIMEN REGISTERED

4. CONFIRM INFO

3A. SPECIMEN DETAILS

2. SELECT SUBJECT TYPE

1. REGISTER HOME

Sub ID: XXXXX is registered
Connected to Sub ID: 123

Register Specimen

Related Subject sub id
All detail entered

Back Confirm

Related to subject? y/n

Field Search Subject Feature

Institution
Physical Location
Received Date
Generation Date
Weight

Uniques confirmed

Confirm Search

Subject Type
O Animal
O Specimen
O Subspecimen

Enroll

(Pop Up Window or Layer from Register Home)

Recent Registers

Register

3B. SUB-SPECIMEN FORM

Related to specimen? y/n

Field Search Specimen Feature

yield concentration
method of isolation

Confirm Search

<ul style="list-style-type: none"> - Register function is selected - Always available to those with the capability 	<ul style="list-style-type: none"> - Pick subject type and click enter 	<ul style="list-style-type: none"> - All required fields marked * - "Submit" sends the info for uniqueness checking - For additional subspecimen fields look to Rose Domain Model - Customer entry fields include: body location, physical location, age, cause of death, patient history, paired/unpaired, dimensions 	<ul style="list-style-type: none"> - If an entry is determined unique, all detail is presented for confirmation. The user can go back to change or confirm to register 	<ul style="list-style-type: none"> - An Sub ID is generated and the specimen is in the pool - Ability to edit after acceptance is possible - Users can do the next one - Sub-specimens in a study - Enroll specimens are automatically enrolled as they must be connected to an enrolled specimen
--	---	--	---	--

Fig 10

ADVANCED SEARCH

Who I Am Where I am		Search (Easy, Advanced)	
Advanced Search			
Keywords: <input type="text"/>			
PATIENT:		Profile Created	
SUID:	<input type="text"/>	First Name:	<input type="text"/>
Enrollment Date:	<input type="text"/>	Last Name:	<input type="text"/>
STUDY:		Condition:	
Study ID:	<input type="text"/>	Procedure:	<input type="text"/>
Study Name:	<input type="text"/>	Study Type:	<input type="text"/>
Data sets:	<input type="text"/>	Start Date of Study:	<input type="text"/>
Approval Date:	<input type="text"/>	<input type="button" value="Search"/> <input type="button" value="Clear"/>	

Fig 11

Open Enrolment Functions

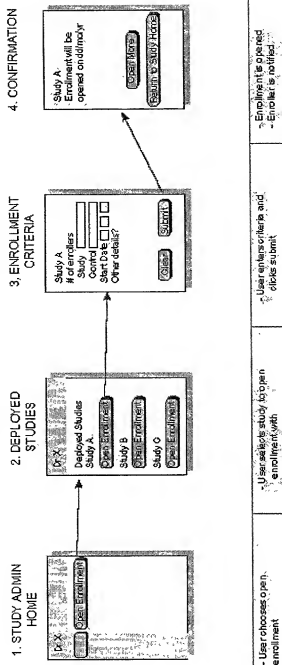
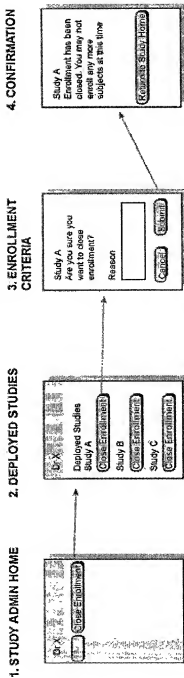


Fig 12

Close Enrollment Functions



- User chooses close enrollment

- User selects study to close enrollment with

- System warns user that they are about to close enrollment.
- User types in reason for closing enrollment

- Enrollment is closed
- Enroller is notified

Fig 13

Role Definition Function

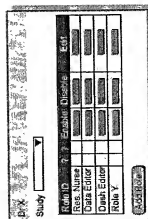
1. ANY PAGE



2. ADMINISTRATION PAGE



3. USER ADMINISTRATION PAGE



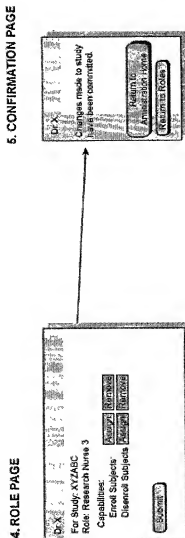
study administrator
checkboxes "Administration" tab

study administrator chooses "roles" tab

study administrator selects study (for which they are a study administrator) that they'd like to manipulate.
System displays roles that are defined (if any) for the selected study. Note we have some space for "TBD" characteristics.
study administrator can add a new role, reconfigurable existing roles, and generally edit the existing roles.

Fig 14a

Role Definition Function (Cont.)

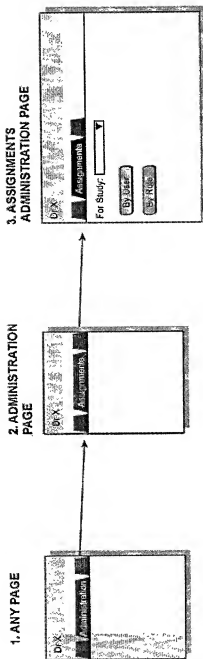


- study administrator selected Add Role or edit an existing role from previous page or
- when study administrator selects Add or Assign or Remove, the system receives the page to indicate updated information
- the final line simply indicates that there are lots of capabilities and we'll need to find a nice model to reflect them.
- More discrete data-oriented capabilities like Edit Data and Review Data capabilities have a sub-table for known data sets (and the ubiquitous transform, assignment, link, or block of text).

- System outlines Role creation / creation

Fig 14b

Role Assignment Function



- First the study administrator will specify the study for which they are assigning roles. The choices in the drop down are those for which they are identified as study administrators.

- They can then specify the assignment role "By User" or "By Role" - both forms are presented as a matter of convenience.

- study administrator chooses "Administration" tab

- study administrator chooses "Assignments" tab

Fig 15a

Role Assignment Function (Cont.)

4A. ROLE ASSIGNMENT BY USER PAGE OR 4B. ROLE ASSIGNMENT BY ROLE PAGE 5. CONFIRMATION PAGE

The diagram illustrates the role assignment process flow. It starts with page 4A, which has a title bar 'Assignments' and a dropdown menu 'For Study: XYZABC'. Below this is a section 'Apply to User:' with a dropdown menu. To the right is a table 'Assigned Roles' with columns for 'Role' and 'Status'. Below the table are 'Assign' and 'Remove' buttons. To the right of the table is a section 'Available Roles' with a table of roles and 'Assign' and 'Remove' buttons. An arrow points from page 4A to page 4B. Page 4B also has a title bar 'Assignments' and a dropdown menu 'For Study: XYZABC'. Below this is a section 'Users With Role' with a table of users. To the right is a section 'Users Without Roles' with a table of users. Below the table are 'Assign' and 'Remove' buttons. An arrow points from page 4B to page 5. Page 5 has a title bar 'Confirmations' and a section 'Changes to roles have been committed' with a 'Return to Role' button.

View if study administrator selected "to user"

- study administrator can Assign/Remove roles by clicking on the "Assign" and "Remove" buttons
- System will refresh page when user Assigns / Removes Roles

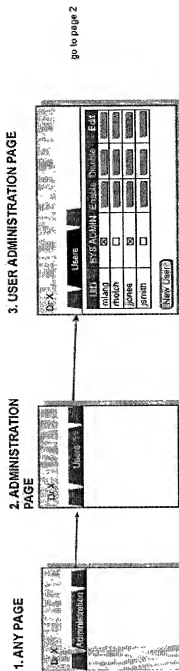
View if study administrator selected "By Role"

- Study administrator can Assign/Remove roles by clicking in the "Assign" and "Remove" buttons (assigning users to the roles)
- System will refresh page when user Assigns / Removes Roles

- System confirms Role assignments.

Fig 15b

User Administration Function



- User chooses
"Administration" tab

- User chooses "Users" tab

- System displays user:

- User can:
 - + add a new user,
 - + enable / disable users,
 - + edit a user. (choosing edit will take the administrator to the next page).

Fig 16a

User Administration Function (Cont.)

4. USER PROFILE PAGE

UID: First Name: Last Name: Email:		Contact Data: _____ _____ _____	
Is System Admin: <input checked="" type="checkbox"/> Is Registrar: <input type="checkbox"/>		Is Study Admin: <input checked="" type="checkbox"/> Studies: Study1 Study2 Study3	
<input type="button" value="Submit"/>			

5. CONFIRMATION PAGE

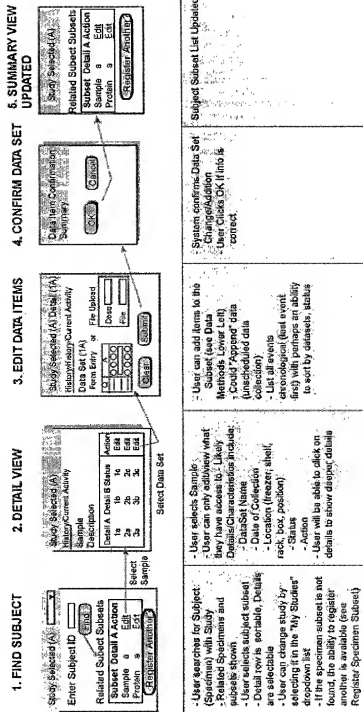
Changes to UID launch have been committed.	
<input type="button" value="Return to
Administration"/>	<input type="button" value="Return to
Main Page"/>

- User could view various aspects of the user's profile.
 - User can click submit to commit changes

- System confirms the commit
 of changes to the user.

Fig 16b

Add/Edit Genetics Data Functions



Review Data Functions

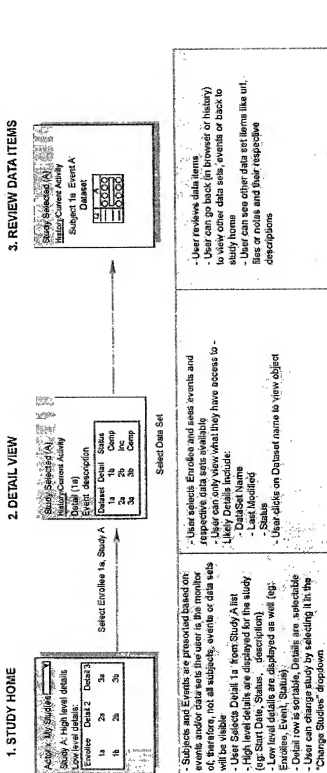
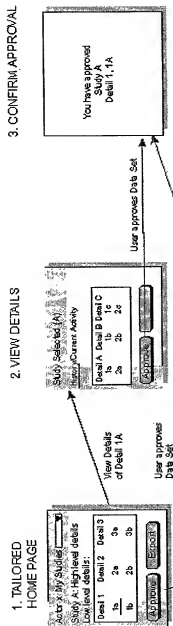


Fig 20

Approve (freeze) Data Set Functions



- User sees current study and the subjects enrolled in that study
- User can approve Data Set from this page
- User can approve Multiple Data Sets at a time
- User can change study by selecting it in the My Studies dropdown list
- User can export data for analysis in an external tool

- System verifies approval

Fig 22

Reinstate Function

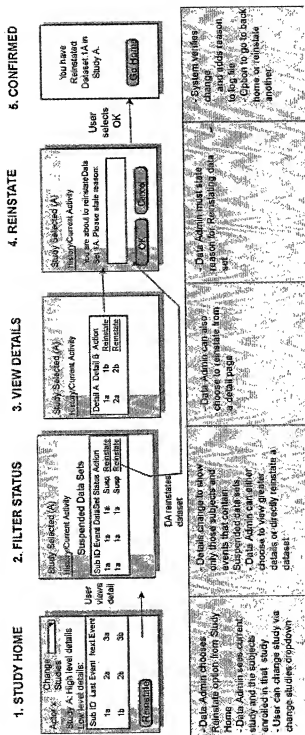


Fig 23

20210-52955001

SCTR
 SPONSORED BY THE
 ARTHRO V-LAR CENTER

SCTR Mail | Preferences | Help | Logout

User: Robert Hatchkiss, MD

Search:

Last Name

GO

Back To

-- Select a Study --

SCTR Mail Message Center

SCTR Mail Home

Post Message

For: Everyone

Priority: Normal

Study: Fracture Callus

Title:

Message:

Close Post

View Messages

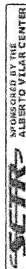
To sort alerts, click on the column header that you wish to sort on.

Study: Basal Joint Arthritis

Date	User	Title	Priority
09/30/2001	hatchkiss	Enrollment for Basal Joint Arthritis Closed	High
09/11/2001	twright	Subject 457342 is disenrolled for study	High
07/23/2001	hatchkiss	Subject 123442 is disenrolled for study	High
08/17/2001	hatchkiss	Collaborator Walter Reed data set Editability Suspended	Normal
06/18/2001	hatchkiss	Subject 123442 is disenrolled for study	Alert
09/23/2001	twright	Enrollment Closed for Basal Joint Arthritis Study	Normal
09/11/2001	hatchkiss	Subject 123442 is enrolled into study	Low
07/23/2001	hatchkiss	Collaborator TIGR data set editability has been Reinstated	Normal

Fig 24

202210'52955001



User: Robert Hitchkiss, MD

SCTR Mail | Preferences | Help | Logout

GO

Last Name

Search:

Back To

-- Select a Study --

SCTR Mail Message Center

SCTR Mail Home

Post Message

For: Priority: Study: Title:

View Message

Date: 09/30/2001

From: rhotchkiss

Priority: High

Title: Enrollment for Basal Joint Arthritis Closed

Message:

Enrollment for the Basal Joint Arthritis Study #445599 has been closed as of 12:30pm 09/20/2001. The maximum number of subjects have been enrolled - we have no further need for subjects at this time.

[Previous Message](#)[Next Message](#)[Archive Message](#)[Close Window](#)

Enrollment for the

Basal Joint Arthritis

Study #445599

Enrollment for the

Basal Joint Arthritis

Study #445599

Enrollment for the

Basal Joint Arthritis

Study #445599

Enrollment for the

Basal Joint Arthritis

Study #445599

Enrollment for the

Basal Joint Arthritis

Study #445599

08/12/2001 rhotchkiss

Collaborator Walter Reed data set editability Suspended

06/18/2001 rhotchkiss

Subject 123442 is disenrolled for study

09/23/2001 twright

Enrollment Closed for Basal Joint Arthritis Study

09/11/2001 leroale

Subject 123442 is enrolled into study

07/23/2001 rhotchkiss

Collaborator TIGR data set editability has been Reinstated

Priority:

High

High

High

Normal

Alert

Normal

Low

Normal

Fig 25

202210-52955001

Enrolled Subject View

Subject ID	First Name	Last Name	Sex	Age	Last Event	Status	Last Event Date	Next Event
123456	Mary	Smith	F	22	Initial Visit	Comp	09/11/2001	Surgery
123455	Brenda	Hadelberg	F	32	Initial Visit	Inc	09/11/2001	Surgery
123454	Helga	Rothchild	F	48	Initial Visit	Inc	09/11/2001	Surgery
123453	Donna	Donaldson	F	67	Surgery	App	09/19/2001	1-Mon Postop
123452	Flora	Dorfman	F	79	1-Mon Postop	Inc	09/11/2001	3-Mon Postop

Total number of enrollees: 27

Scheduled Event Status View

EVENT	DATA ENTRY STATUS		
	TBE	Incomplete	Approved
Initial Visit	18	22	5
Surgery	4	5	12
1-Mon Postop	12	3	9
3-Mon Postop	2	3	2
1-Yr Postop	3	0	1
2-Yr Postop	3	0	0
3-Yr Postop	3	10	0

Fig 26

Manage Subjects

Change Studies

View All Studies

Study: 445599 Basal Joint Arthritis

Manage Subjects: Subject View

Subject 123456

General Characteristics

Sex: Female
Age: 20
Race: Caucasian
Height: 6'00
Weight: 125
Eye Color: Brown

Personal Info

Associated Medical Info

Event List

Scheduled Events

Event	Data Status	Last Modified
Initial Study Visit	Inc	04/08/1998
Surgery	TBE	04/10/1998
1-Mon Postop	Comp	04/11/1998
3-Mon Postop	Comp	04/10/1998
1-Yr Postop	Inc	04/10/2000
2-Yr Postop	Comp	04/10/2001

Event Last Modified

Event Name	Modified
Physical Exam	04/08/1998
Surgery	04/10/1998

Add Unscheduled Event

Study: 445599 Basal Joint Arthritis
Subject: 123456
Event: Initial Study Visit

Problem:

SCTR Administrator

Join Date

Total Events

Fig 27

202210"52955001

SCTR Mail | Preferences | Help | Logout

SCTR
 SPONSORED BY THE
 ALBERTO VILAR CENTER
 User: Robert Hatchkiss, MD

Search: Last Name

Manage Subjects
Study: 445599 Basal Joint Arthritis
Manage Subjects: Add Unscheduled Event
Subject 123456

Add Unscheduled Event

Event Name:

Change Studies
 View All Studies

Manage Subjects

Candidates

Find

Enroll

View

Disenroll

Events

Choose

View Scheduled

View Status

Add Unscheduled

Drop Sets

Choose

Edit

Approve

Indirect Approval

Sponsored by the
 Alberto Vilar Center
 for Research in
 Musculoskeletal Subjects

Problems?
 SCTR Administrator
 Add Date

Legal Notice

Fig 28

20E2T0.5295500T

Manage Subjects
Study: 445599 Basal Joint Arthritis
Manage Subjects: Add Unscheduled Event Confirmed
Subject 123456

Add Unscheduled Event Confirmed
The Unscheduled Event Thumb Check-up has been successfully added.
Study: 445599 Basal Joint Arthritis
Subject ID: 123456
[Return to Subject View](#) [Return to Event View](#)

Change Studies
[View All Studies](#) [Add](#)

Manage Subjects
[Candidates](#)
[Find](#)
[Enroll](#)
[Enroll](#)
[View](#)
[Disenroll](#)
[Events](#)
[Choose](#)
[View Scheduled](#)
[View Status](#)
445 Unscheduled
[Data Sets](#)
[Choose](#)
[Edit](#)
[Approve](#)
[Retract Approval](#)

For more information, please contact the SCTR Administrator at 1-800-555-1234.

Implications:
SCTR Administrator
1/1/2010

Log Out

Fig 29

Manage Subjects

Study: 445599 Basal Joint Arthritis

Manage Subjects: Subject View

Subject 123456

General Characteristics

Sex: Female
Age: 20
Race: Caucasian
Height: 6'00
Weight: 125
Eye Color: Brown

[Personal ID Info](#)
[Associated Medical Info](#)

Event List

Event	Data Status	Last Modified
Initial Study Visit	Inc	04/08/1998
Surgery	Inc	04/10/1998
1-Mon Postop	TBE	04/11/1998
3-Mon Postop	Comp	04/10/1999
3-Mon Postop	Comp	04/10/1999
1-Yr Postop	Inc	04/10/2000
2-Yr Postop	Comp	04/10/2001

Unscheduled Event

Event Name	Modified
Physical Exam	04/08/1998
Surgery	04/10/1998
Thumb Check-up	10/25/2001

[Add Unscheduled Event](#)

Change Studies

[View All Studies](#)

Manage Subjects

Candidates

[End](#)
[Enroll](#)
[View](#)
[Disenroll](#)
[Events](#)
[Choose](#)
[View Scheduled](#)
[View Stable](#)
[Add Unscheduled](#)
[Data Set](#)
[Edit](#)
[Choose](#)
[Approve](#)
[Rebut Approval](#)

Sponsored by the Alberto Vilar Center for Research that supports the study of Basal Joint Arthritis. SCIR Administrator: J. Hotchkiss, MD

Fig 30

Fig 31a

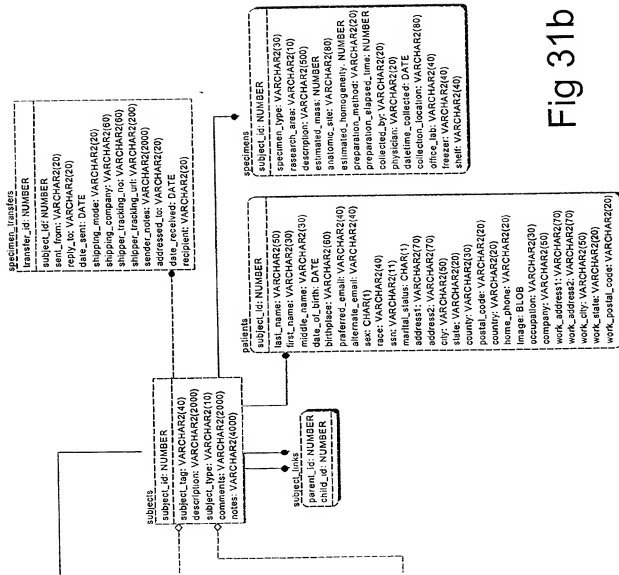


Fig 31b